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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : James Richard Jackson
SERIAL NO. : 09/381,561 EXAMINER: Christopher L. Chin
FILED : September 17, 1999 ART UNIT : 1641
FOR : RECORDING ASSAY DEVICE

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David A. Jackson, Reg. No. 26,742
(Name of Registered Rep.)

Leis A. Anure 1/3/03
(Signature and Date)

SUBMISSION OF SUBSTITUTE APPEAL BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
BOX APPEAL
WASHINGTON, D.C. 20231

Dear Sir:

Responsive to the Communication of December 3, 2002 from the Examiner, Applicant Appellant hereby submits a substitute Brief on Appeal in triplicate, to be entered and considered in place of the Brief on Appeal that was mailed on September 3, 2002.

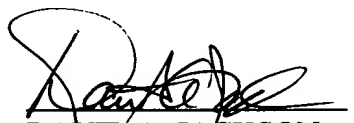
In particular, the undersigned attorney for Applicant Appellant has revised the Summary of the Invention in accordance with the Examiner's comments, to identify those passages of the specification and those drawings where the claimed elements are set forth and described or depicted. It is believed that these corrections place the Brief into full compliance with the relevant rules, and should enable the consideration of the merits of the case to proceed.

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As the previous submission included the payment of the requisite fee for the filing of the Brief, an additional fee is not believed to be needed. Should additional fees be due and payable, however, authorization is hereby given to charge Deposit Account No. 11-1153 of the undersigned.

Favorable consideration of the attached Brief and continued processing of the subject Appeal are courteously solicited.

Respectfully submitted,



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Enclosures: Brief on Appeal in Triplicate



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

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TECH CENTER 1600/2800

In re the Application

Inventor : James Richard Jackson
Application No. : 09/381,561
Filed : September 17, 1999
For : RECORDING ASSAY DEVICE

APPEAL BRIEF

On Appeal from Group Art Unit 1641

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I. REAL PARTY IN INTEREST

The real party in interest is the applicant of the present application, James Richard Jackson.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 20-39 have been presented for examination. All of these claims are pending, stand finally rejected, and form the subject matter of the present appeal.

IV. STATUS OF AMENDMENTS

The Request for Reconsideration filed May 13, 2002, in response to the Final Rejection dated February 1, 2002 did not contain any amendments to the application, and did not place the application in condition for allowance.

V. SUMMARY OF THE INVENTION

The claimed invention comprises an assay part that permits tissue or fluid samples to be recorded for subsequent transmission for analysis at a remote data processing site. One advantage of the present invention is that high quality medical diagnosis can be performed in remote areas that otherwise lack state of the art medical facilities. Also, patient privacy is protected, both by those handling the recording

device and the patient himself, particularly if the recording device is used to record indicia of drug used, such as opiates.

As shown in Figure 1 and in the specification at page 8, lines 21-26 , the assay part comprises at least one sample application well (1) that is in fluid connection with at least one primary assay reagent conduit (2). Also, as described in the specification at page 9, line 9 to page 10, line 9, the primary assay reagent conduit may comprise any of filter paper impregnated with the assay reagent, or any of (i) multiple channels formed in water permeable material by impregnation with polymers to form a water impermeable region; (ii) multiple channels formed in nitrocellulose or other water permeable diagnostic or filter membrane; (iii) formation of strips of water permeable material within a sheet of material by cutting regions from a sheet of the material to form multiple channels; (iv) printing (e.g. by silkscreen) of a water permeable material used to make diagnostic and filter membranes in emulsion or other fluid formed onto a water impermeable surface to create channels of water permeable material; (v) multiple water permeable channels; (vi) a single channel strip having multiple detection zones; (vii) a channel of free space within a water impermeable material forming a capillary flow device, as some examples.

A secondary reagent conduit (3) (see specification, page 10, line 16 and following, and Figure 1) may be present to provide a reaction of secondary reagents required to complete the assay. A testing indicator (4) (a.k.a. detection zone) (specification, page 9, lines 25-27) is arranged to indicate to the user/patient that a suitable sample has been assayed, so that the patient knows there is enough tissue/fluid sample provided to complete the assay. An optional waste-well (5) may be provided to store excess sample/reaction mix.

As shown in Figure 2a and 2b (now renamed Figures 2 and 3, respectively) and as described in the specification at page 12, lines 7-9 and 20-23, a detachable recording part, which is detachable from the rest of the assay device, records the assay information without analyzation thereof in a form suitable for onward transmission for subsequent processing at a remote processing site. In the embodiment shown in Figure 2b (Figure 3), it can be seen that after the test indicator (9) has indicated that an assay has been performed on a suitable sample, attachment means (11) (specification, page 12, lines 22-23) may be perforated to assist in detaching the assay part from the detachable recording part. The recording part is a data storage means (specification, page 12, lines 3-4) and does not include the facility to analyze the conducted assays.

Figure 2A (Figure 2) and page 12, lines 8-13, describe the alternate embodiment of the device as set forth in e.g. appealed claims 34 and 35, where different assay reagents may be used so that multiple testing of variables from a particular sample may be conducted. Each of the conduits (6) contain a detection zone (4) that is connected to a microprocessor (8); see also, specification, page 12, lines 13-15.

After the data in the recording part is onwardly transmitted, the recording part can be returned to the patient and re-connected to the assay part to permit a series of monitored events and/or subsequent further testing. Treatment to the patient can be reviewed and adjusted/alterd according to the results of the analyzation, with a unique cost savings by the onward transmission of data from the recording part, as well as benefiting patients with mobility problems or residing a considerable distance from an adequate testing facility.

VI. ISSUES

1. Whether claims 20-39 stand properly rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Chow (U.S. 5,955,028).

2. Whether claims 20-39 stand properly rejected under 35 U.S.C. §103(a) as allegedly being obvious over the combination of Hillman et al. (U.S. 4,756,884 hereafter "Hillman"), Galen et al. (U.S. 5,695,949 hereafter "Galen"), and Phillips et al. (U.S. 5,179,005 and U.S. 5,426,032, hereafter referred to as "Phillips'005" and "Phillips'032" or collectively as "Phillips").

VII. GROUPING OF CLAIMS

Claims 1-37 ^{should be} stand or fall together, as they recite an assessment device comprising a detachable recording part. Claim 38, which recites a method to assay and record a tissue/fluid sample, stand or falls alone. Claim 39, which recites a kit containing the assessment device according to any of claims 1-37, stands or falls alone.

VIII. ARGUMENT

35 U.S.C. §102(e):

1. With regard to the rejection of claims 20-37 ^{should be} under 35 U.S.C. §102(e) in view of Chow, the Examiner alleges in the Final Rejection and in the Advisory Action that Chow anticipates the metes and bounds of the rejected claims. Applicant respectfully but strongly disagrees, *infra*.

In the Office Action dated 5/22/01, in which the Examiner lays the foundation for the rejection of the instant claims in view of Chow, the Examiner asserts "Chow

discloses a base unit to interface an assay substrate with a recording device, such as a computer. Chow discloses an assay substrate (assay part) that is removable from a computer (recording part); therefore, Chow anticipates the invention as claimed."

First, it is respectfully submitted that Chow clearly discloses *an analytical system* comprising: a base unit, an adapter, and a sample substrate (column 4, lines 10-12). The base unit disclosed in Chow analyzes data, and in column 2, lines 21-29 is referred to as a "base analytical unit." Further, the computer (alleged to be analogous to Applicant's recording part) is not a detachable recording part that "*only records the said assay information without analyzation there of in a form suitable for onward transmission for subsequent processing and analysis at a remote data site*" as recited by present claim 1.

An advantage of the present invention is that *analysis* is not part of the device, so as to reduce costs, size, and make the device usable at remote locations where a patient could simply send the detachable recording part to a remote site for subsequent processing. This feature contrasts with a personal computer attached to the base unit.

In fact, Applicant respectfully submits that that the computer (as well as the base unit) disclosed by Chow are stationary, and it is the adapter that is removable from the base unit (please see column 3, lines 18-21, and Figure 3). It is respectfully submitted that the logic used to allege that the computer is a detachable recording part because the adapter can be disconnected from the base is counter-intuitive, and is akin to saying that if a dog wags its tail, that it is also true that its tail wags the dog.

With regard to the Examiner's assertion in the Final Rejection dated February 1, 2002 that "Applicant's argument is essentially directed to how the device of Chow is being used versus how the instantly claimed invention is being used" because

analysis of collected data on site in Chow versus analysis of collected data at a site other than where the data is collected is a method of use, is in the respectful opinion of the Applicant, flawed. Applicant is arguing claimed limitations, not intended use. For example, in claim 21, the detachable recording part is "sized to facilitate personal handling by one of said user and a technician, and to facilitate transport of said recording device to a processing facility by a common courier." Such a limitation is surely not an intended use. Furthermore, Chow discloses at column 5, lines 60-66 that the computer controls the assay, and "thus the present invention comprises the computer program itself" which may be used in combination with the system. This disclosure in Chow contrasts with the lack of analyzation by the recording part in the presently claimed invention, so as to make the device less expensive, smaller, and able to provide improved healthcare to persons in remote areas that do not have testing facilities to house stationary devices such as that disclosed by Chow.

Additionally, according to the Rule of Subtraction, Applicant is claiming fewer features than is taught in the prior art such as Chow, and is therefore patentable. In addition, Chow fails to disclose or suggest at least the additional recitation in claim 23 that the recording part is in retrofit form.

Chow also fails to disclose the method recited in claim 38, particularly the recitation that there is an application of sample to at least one sample application well of an assay part of an assessment device according to claims 20-37.

Finally, it is respectfully submitted that Chow fails to disclose or suggest the recitation in claim 39 that a kit comprises an assessment device, assay reagents and protective packaging for transport of the recording device to a processing facility.

Accordingly, it is respectfully submitted that none of the instant claims are anticipated by Chow, as this reference fails to disclose all of the elements recited by

Applicants claims. It is also respectfully submitted that none of the instant claims would have been obvious to a person of ordinary skill in the art in view of Chow.

As held by the Court of Appeals for the Federal Circuit held in *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628,631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987):

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

For the reasons previously indicated, the Final Office Action fails to set forth each and every claimed element in a single reference. It is respectfully requested that this Honorable Board withdraw of this ground of rejection.

35 U.S.C. §103(a)

2. With regard to the rejection of claims 20-39 stand properly rejected as over the combination of Hillman and either Phillips, it is respectfully submitted that none of the instant claims would have been obvious to a person of ordinary skill in the art at the time of the invention in view of the combination of references.

The Examiner alleges that all of Hillman, Galen or Philips disclose a detachable recording part. It is respectfully submitted that the Examiner's assertion (on page 7 of the Office Action dated 5/22/01) that the fact that Hillman discloses at column 17, lines 40-52 that an LED photodetector and semi-conductor laser can be employed to detect a speckle pattern, and that a housing for the LED photodetector and semi-conductor laser "may include a housing for receiving and holding the device" inherently discloses a detachable recording part, cannot be rationally deduced

from the cited passage of the reference. First, there is no disclosure about recording the detected speckle pattern for subsequent analyzation at a remote data processing facility. Second, because the housing may allow for insertion of the assay for analysis, and subsequent removal, does not transform the LED photodetector into a detachable recording part. The LED photodetector and semi-conductor laser is not forwarded to a data processing facility for subsequent analysis. The shipment of a laser and LED photodetector to a remote site is not disclosed by Hillman, nor would it make any sense to do, as the advantages of the presently claimed invention would not be realized.

With regard to Galen and Phillips, Fig. 4 of Galen shows a glucose testing device that is not a detachable recording part as presently claimed. The device 28, analyzes the sample and provides a display. This device contrasts with the instant claims, where the detachable recording part does not analyze the sample and merely stores collected data for a subsequent testing at a remote location. The entire idea of Galen is to provide the analysis to the user on the spot. In addition, any storage taught by Galen is of the *analysis* of the test results, which is distinguishable from that which is recorded by the detachable part of the presently claimed invention.

Finally, with regard to Phillips, Applicants respectfully disagree that Figs. 3 and 4 disclose a detachable recording part as presently claimed. These two Figures show diabetic testing devices that *analyze* a sample and provide results to a user on site. This teaching is different from a detachable recording part that records but does not analyze the sample. Further, any storage in Phillips would be of the result of the analysis, not the recordation of the sample.

Accordingly, it is respectfully submitted that none of the present claims would have been obvious to a person of ordinary skill in the art of the combination of

teachings of Hillman, Galen, and Phillips because the references would not have provided an artisan with any teaching, disclosure or motivation to combine their teachings. Assuming *arguendo*, even if an artisan were to have combined the teachings of the references, such a combination would not have caused any of the present claims to be obvious in view of the combination. The suggestion or motivation to modify the references must be found in the references themselves, or be inherent in the art, and in either case, the combination of references and the art fails to make any such disclosure, suggestion, or motivation.

Applicants note that it was held by the Court of Appeals in *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992) that:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so. Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

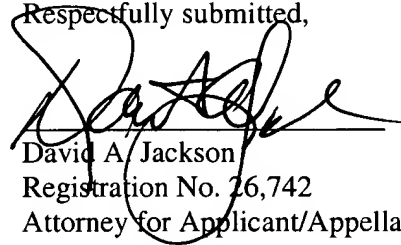
In the present case, it is respectfully submitted that the teachings of the combination of references do not overcome the standard of establishing obviousness as exemplified in *Fritch*.

For the above reasons, it is respectfully requested that this Honorable Board reverse this ground of rejection.

IX. CONCLUSION

Based on the above analysis of the law and the facts, it is respectfully requested that this Honorable Board reverse all grounds of rejection with regard to the present application.

Respectfully submitted,



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Date: January 3, 2003

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X. APPENDIX: THE CLAIMS ON APPEAL

20. An assessment device comprising an assay part adapted to undertake an assay wherein said assay part comprises:

at least one sample application well in fluid connection with at least one primary conduit, wherein either, or both of said application well and said primary conduit, contains material for assaying a fluid sample;

a test ready indicator for determination by a user when a sample has been suitably assayed; and

a recording part which is detachable from said assay part for the storage of assay information generated by said assay part relating to at least to said sample after said assay has been completed, and wherein said recording part is in data communication with said assay part when attached to said assay part to enable transfer of assay information from said assay part to said recording part for storage;

wherein said recording part only records the said assay information without analysis thereof in a form suitable for onward transmission for subsequent processing and analysis at a remote data processing site.

21. An assessment device according to claim 20 where the detachable recording part is sized to facilitate personal handling by one of said user and a technician, and to facilitate transport of said recording device to a processing facility by a common courier.

22. An assessment device according to claim 20 wherein said recording part is provided with data communication control means to facilitate the electronic downloading and transfer of data to a processing facility.

23. An assessment device according to claim 20 wherein said recording part is in retrofit form.

24. An assessment device according to claim 20 wherein said recording part is an electronic storage device.

25. An assessment device according to claim 20 wherein said recording part is a microchip or a microprocessor.

26. An assessment device according to claim 20 wherein said recording part is a photographic recording means.

27. An assessment device according to claim 20 wherein said assay part comprises multiple sample application wells.

28. An assessment device according to claim 27 wherein at least one of said sample application wells is impregnated with material for assaying a fluid sample.

29. An assessment device according to claim 27 wherein said primary conduit contains reagents for diluting said sample fluid.

30. An assessment device according to claim 27 having a primary conduit wherein said primary conduit is suitable sized to facilitate capillary flow of said sample fluid therethrough.

31. An assessment device according to claim 27 wherein said assay part is provided with at least one secondary conduit which is in fluid communication with one or more of said sample wells.

32. An assessment device according to claim 31 wherein said secondary conduit is suitable sized to facilitate capillary flow of said sample fluid therethrough.

33. An assessment device according to claim 31 wherein said secondary conduit contains assay reagents.

34. An assessment device according to claim 33 wherein said primary conduit contains at least one assay reagent, and wherein said assay reagents of said secondary conduit are of a different nature than said at least one assay reagent in said primary conduit.

35. An assessment device according to claim 34 wherein said assay reagents are compatible with the assay reagents of the primary conduit so as to provide, in total, for the complete and selected assaying of said fluid sample as it flows through at least one of the primary and secondary conduits.

36. An assessment device according to claim 20 wherein said assessment device includes at least one control or calibration means.

37. An assessment device according to claim 20 wherein said assay part is provided with at least one detection zone to facilitate detection of the results of an assay.

38. A method to assay and record a tissue/fluid sample comprising:

- i) applying a sample to at least one sample application well of an assay part of an assessment device according to claims 20-37;
- ii) mixing said sample with at least one primary assay reagents;
- iii) generating assay information relating to said sample; and
- iv) Recording the assay information via the recording part of the assessment device.

39. A kit comprising an assessment device according to any of claims 20-37 comprising an assessment device, assay reagents and protective packaging for transport of the recording device to a processing facility.